COMPARATIVE EFFICACY OF SYNTOMETRINE VERSUS OXYTOCIN IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR

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CERTIFICATE

This is to certify that the dissertation titled "**COMPARATIVE EFFICACY OF SYNTOMETRINE VERSUS OXYTOCIN IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR"** is the bonafide work done by **Dr. V. ARUNA DEVI** between September 2008 to August 2009 during her M.D.,O.G., course at ISO - KGH, MMC Chennai.

DEAN

MADRAS MEDICAL COLLEGE

DIRECTOR

INSTITUTE OF SOCIAL OBSTETRICS

KASTURBA GANDHI HOSPITAL

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I thank **my family & friends** for their inspiration & support given to me.

ETHICAL COMMITTEE CERTIFICATE

NO;;

DATED;

I,DR.V.ARUNADEVI apply for the ethical committee certificate for the project"COMPARATIVE EFFICACY OF SYNTOMETRINE Vs OXYTOCIN IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR" under the guidance of Dr.Vasantha N. Subbiah M.D.DGO,Director ,Institute of Social Obstetrics,Govt.Kasturba Gandhi Hospital ,Triplicane,Chennai-5

I understand the implications of doing research with human subjects and willfully comply with the regulations and keep the dignity and protect the health of subjects at all costs.

Signature of the post graduate Student

I Have no objection to guiding this postgraduate student in the project mentioned above.I Shall pervise to the extent that all the human rights are protected and research is carried on with utmost humanitarian principles.

Signature of the Guide

Seal of Guide

Senior Civil Surgeon
Institute of Social Obstetrics and
Govt. Kasturba Gandhi Hospital for
Women, [illegible], Chepauk,
Triplicane, Chennai-600 005

I Certify that this project has been presented in front of the Ethical Committee on duly formated in this Institution and that all the members of the ethical committee have given permission to conduct this research.

CHAIRMAN ETHICAL COMMITTEE

Professor & Head
Dept. of Community Medicin
Stanley Medical College
Chennai-600 001.

Date

Seal

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INTRODUCTION

INTRODUCTION

Postpartum hemorrhage is a major obstetrical complication & one of the important but preventable causes of maternal morbidity & mortality. It occurs suddenly, often is unpredictable & can lead to maternal death if it is severe & untreated. Globally it is estimated that severe PPH (Postpartum hemorrhage) occurs in about 11% of women who give a live birth. The incidence is thought to be much higher in developing countries where many women do not have access to a skilled attendant at delivery and where active management of the third stage of labor may not be routine. It is estimated that about 14 million women suffer severe blood loss postpartum, and that 1% of these die as a result. A further 12% survive with severe morbidity.

Uterine atony remains the most common cause of PPH. Adequate retraction of uterus in third stage of labor is essential for separation of placenta & control of third stage bleeding as well as for prevention of PPH. A prolonged third stage of labor is often associated with increased risk of maternal mortality & morbidity due to atonic PPH. In modern obstetrics judicious use of oxytocics & active management of third stage of labor is strongly recommended especially in women who are at risk of uterine atony. Routine administration of oxytocics reduces the risk of PPH by 40%. Although routine use of oxytocics has become widespread for shortening third stage

of labor, the choice of oxytocin preparation, its efficacy & mode of administration varies.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

PPH is a nightmare to every obstetrician as it is sudden, frequently unpredicted & could be catastrophic. In the early decades of 20th century, PPH was the most common cause of maternal death (Thilaganathan et al[1] -1993).

The objective of prophylactic oxytocics is to ensure efficient contraction of the uterus after delivery of infant, thus minimizing the amount of blood loss due to failure of occlusion of capillaries in placental site & promote rapid separation & descent of placenta.

Lister, Martin & Dumoulin[2] (1981) established that intravenous ergometrine given with crowning of head or anterior shoulder reduces the risk of hemorrhage.

Embrey et al[3](1963) have shown that the incidence & severity of PPH in a group of normal patients given i.m syntometrine (5u of oxytocin with 0.5 mg of ergometrine) with birth of anterior shoulder, was significantly less than in a similar group of cases given i.m ergometrine.

Fleigner & Hibbard[4] (1966) compared the advantages & disadvantages of traditional method versus the use of controlled cord traction with syntometrine.

There was reduction in incidence of PPH from 5% to less than 2%. There was no increase in need for manual removal of placenta or in incidence of retained cotyledons or membranes.

Sorbe[5] (1978) recommended that administration of oxytocics will remain a cornerstone in active management of third stage of labor. He suggested that oxytocin i.v. in adequate doses offered some advantage over ergometrine as it caused undisturbed physiological placental separation.

Neri et al[6] (1966) introduced a new method of giving 5 units of oxytocin into umbilical vein to enhance separation of placenta. This method has been tried by many people later for management of third stage and routinely for treatment of retained placenta.

Golan et al[7] (1983) administered 10 units of oxytocin diluted in 20 ml of normal saline into umbilical vein in 10 patients who had retained placenta for 30 minutes after delivery. In all cases studied, expulsion of placenta occurred in a few minutes. The average injection-expulsion interval was 3 minutes 40 seconds (range 2-5 minutes).

Using intraumbilical oxytocin 80% of patients for whom manual removal of placenta was indicated otherwise, were spared of the risks of general anaesthesia and other associated risks of manual removal like immediate trauma to the uterus and increased incidence of puerperal infection.

Hauksson et al[8] (1986) evaluated this method in 48 patients with placenta retained in uterus for 60minutes after birth. In 22 women the placenta was completely expelled within 9 to 50 minutes (mean19 minutes) after intraumbilical injection. Rest of them required manual removal, which was clearly more difficult than usual because of firmly contracted uterus. No cardiovascular or other side effects were noted but one patient required immediate manual removal as she had severe PPH. The possible explanation for very good results of Golan et al appears to be due to early timing of umbilical vein injection.

Chesnut et al[9] (1987) in a randomized double blind placebo controlled study evaluated the influence of umbilical vein administration of oxytocin on the third stage of labor. There was no significant difference in mean injection-placental expulsion interval.

Young et al[10] (1988) performed randomized studies of prophylactic

Umbilical vein oxytocin and showed no benefits.

Thilaganathan et al[1] (1993) compared active management using syntometrine & controlled cord traction with physiological management of third stage of labor in women at low risk for PPH. There was no significant difference in the estimated blood loss or hemoglobin drop between the 2 groups. The duration of third stage was significantly longer in physiological group.

A prospective study[11] (2008) was carried out at Prince Zaid Ben Al-Hussein Hospital, Tafilah, Jordan. Two thousand one hundred and sixty one women delivering singletons during 12 consecutive months were included in their study. Women received either intramuscular syntometrine or intravenous oxytocin alone. The drugs were used either before or after the 3rd stage of labor, in order to compare their safety and efficacy in prevention of PPH. There was no significant difference in the rate of PPH for syntometrine compared to oxytocin, when used at the end of 2nd stage of labor (odds ratio 1.08, 95%confidence interval 0.72-1.63) or after the 3rd stage (odds ratio 0.93, 95% confidence interval 0.65 – 1.34).The patients receiving oxytocics at the end of 2nd stage of labor had significantly lower rates of PPH ,for both syntometrine (odds ratio 0.86, 95%CI 0.59-1.12) and oxytocin (odds ratio 0.59, 95% CI 0.39-088), compared with those treated after 3rd stage. Oxytocin alone is as

effective as the use of syntometrine in prevention of PPH, but associated with significantly fewer maternal side effects. Oxytocics administered after the 2nd stage of labor compared with after the third stage (placental expulsion) are associated with a significantly fewer rate of postpartum bleeding.

The efficacy of syntometrine has been shown to be significantly reduced when it is stored in a suboptimal environment (Chua et al[12] 1993).

Oral administration of ergometrine has been shown to be ineffective in reducing postpartum blood loss (de Groot et al[13], 1996) and oral preparation is not stable under simulated tropical conditions (de Groot et al[14], 1995), making it unsuitable for tropical conditions.

In a randomized controlled study[15] performed in three tertiary training centers in Hong Kong, 2058 patients were recruited into the study and randomized to either oral misoprostol or i.m syntometrine. There was no significant difference in the amount of blood loss and the incidence of PPH (> 500ml) or severe PPH (> 1000ml) in both groups. A multiparous patient in syntometrine group developed massive postpartum hemorrhage of 5 liters after a normal vaginal delivery because of uterine atony and required an abdominal hysterectomy. The incidence of prolonged third

stage (> 30minutes) was similar. The incidence of nausea, vomiting, headache and chest pain was low and similar in both groups. Twenty patients in misoprostol group developed high fever (> 39°C), compared to only one patient who had a temperature of 38C in syntometrine group. The incidence of blood transfusion was 1.5 and 1.6% respectively.

The review by McDonald et al[16] comparing syntometrine & oxytocin revealed that the use of intramuscular syntometrine was assoiated with reduced risk of PPH with a summary odds ratio of 0.74 (95%CI-0.85), regardless of the dose of oxytocin used.

In most of the early studies comparing oxytocin with syntometrine in the prevention of PPH, oxytocin was given i.m at a dose of 5units.In the study published by Dumoulin [2] in 1981, it was clearly stated that the dose of i.m oxytocin had to be changed from 5 units to 10 units during the course of trial because of higher incidence of PPH with the lower dose (12.4% versus 8.6%).

In a series of 1378 subjects, Nieminen &Jarvinen[17] reported no difference in the PPH rate between the two drugs when given intramuscularly with an odds ratio of 0.56 (95%CI 0.20-1.61).

In a double blind randomized controlled trial involving 461 patients, Mitchell et al[18]reported a significant reduction in PPH rate in the syntometrine group with an odds ratio of 0.37(95%CI 0.16-0.85).Combining these studies, i.m syntometrine was associated with a significantly lower rate of PPH than 5 units of oxytocin alone, with an overall summary odds ratio of 0.36 (95%CI 0.23-0.55).

Docherty and Hooper[19] (1981) reported that oxytocin was associated with a 40% increase in mean blood loss, but absolute rate of PPH was not stated.

McDonald et al and Khan et al[20] (1995) reported no difference in PPH rate with an odds ratio of 0.90 (95%CI 0.75-1.07) and 0.89 (95%CI 0.53-1.51), respectively. However, the use of syntometrine was associated with an increase in the incidence of nausea, vomiting, headache &hypertension.

Yuen et al[21] (1995) reported a 40% reduction in the risk of PPH (OR 0.60, 95%CI 0.21-0.88) & the need for repeated oxytocic injections (OR 0.63, 95%CI 0.44-0.89) in the syntometrine group compared to oxytocin & side effects were

uncommon in both groups. The overall comparison of 10 units of intramuscular oxytocin with syntometrine still favors syntometrine (OR 0.81, 95%CI 0.70-0.94).

A randomized control study[22] (2004) was carried out comparing the efficacy and side effects of sublingual misoprostol and intravenous methylergometrine for active management of third stage of labor in 120 low risk pregnant women at term, with spontaneous onset of labor. The women were randomized to receive either two tablets of misoprostol (200microgram/tablet) sublingually or 1ml of methylergometrine (0.2 mg) intravenous injection, after the delivery of anterior shoulder of the baby. Postpartum hemorrhage as defined by hemorrhage>500ml occurred in 3.1% of the women in sublingual misoprostol group but none of the women in methylergometrine group ($p>0.05$). There was a need for additional oxytocic drugs in 5% and 8.3% after methylergometrine and misoprostol, respectively ($p>0.05$). The change in hemoglobin levels at 24hr postpartum were 0.8 and 0.7 gm% in methylergometrine and misoprostol group, respectively ($p>0.05$). In the misoprostol group, 6.6% women developed fever >38 degree C and 21.6% had shivering while in methylergometrine group none experienced these side effects. Sublingual misoprostol appears to be as effective as intravenous methylergometrine in the prevention of PPH. However, larger randomized studies are needed to advocate its routine use.

A Cochrane Review[23] (2004) of misoprostol versus oxytocin included 24,100 women and compared various oral and rectal doses of misoprostol with injectable oxytocin. They found that 600 microgram of misoprostol was less effective than oxytocin in preventing PPH greater than 1000ml (RR, 1.36; 95%CI, 1.17-1.58). It was found that 3.6% of those given 600 microgm misoprostol had a blood loss greater than 500ml compared to 2.6% of those given oxytocin.

A randomized controlled trial[24](2004) in Mozambique found that rectal misoprostol (400mg as rectal enema) was as effective as 10 IU oxytocin given i.m in preventing PPH. Blood loss ,duration of third stage, or hemoglobin and hematocrit at 72 hours postpartum were not significantly different between the groups.

A randomized controlled trial[23] from Turkey found that oral misoprostol was as effective as oxytocin alone in preventing PPH, but not as effective as oxytocin plus methylergonovine maleate or oxytocin plus oral misoprostol. A review of misoprotol use during third stage of labor, compared with both placebo and oxytocin or syntometrine, found that misoprostol is better than placebo in reducing the need for additional oxytocics but inferior to oxytocin in preventing PPH, and it requires more additional use of oxytocics than syntometrine.

Cochrane Database Syst Rev.2000 reported that the use of combination preparation syntometrine as part of routine active management of third stage of labor (AMTSL) appears to be associated with a statistically significant reduction in the risk of PPH when compared to oxytocin where blood loss is <1000 ml. This needs to be weighed against the more common adverse effects associated with the use of syntometrine.

Edgardo Abalos[25] stated that the use of syntometrine as part of AMTSL is associated with significant reduction in the incidence of PPH (blood loss >500ml) compared with oxytocin alone, irrespective of the dose (5units or 10units). No difference was observed in severe PPH (>1000ml). However the addition of ergometrine increases the incidence of high B.P & vomiting & these undesirable effects should be taken into account in determining the best therapy. The main results of the review can be summarized as follows: when 100 women were treated with syntometrine rather than oxytocin alone, 3 additional episodes of blood loss>500ml will be prevented. But at the same time one additional case of high B.P & 10 additional cases of vomiting will be observed.

Abudhabi third stage trial[26] reported that, prophylactic administration of oxytocin 10units as part of AMTSL, reduces the incidence of maternal nausea,

vomiting & headache & rise in blood pressure than does syntometrine 1ml without adversely affecting the rate of PPH.

A clinical trial[27] was designed to study 618 patients admitted to Zahedon Ghods Birth Center in 2001 for normal delivery. The patients were randomly divided into two groups. All pregnancies were singleton, normotensive and free from medical disease. After exiting the anterior shoulder of fetus, 5IU of oxytocin in the first group and 0.5mg ergometrine plus 5IU of oxytocin in the second group was injected intramuscularly. Among the first group there were 20 cases (6.47%) with abnormal hemorrhage, compared to 8 cases (2.58%) in the second group. There was a significant difference between the two groups in postpartum hemorrhage. There was no significant difference between two groups concerning the duration of third stage and the need for manual removal. The side effects were uncommon and the incidence of hypertension was not different between two groups. The results showed that syntometrine is more effective than oxytocin in preventing postpartum hemorrhage.

POSTPARTUM HEMORRHAGE

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Definitions:

Loss of 500ml or more of blood per vaginum during the first 24 hours after delivery of baby or even if blood loss is <500ml but associated with significant hemodynamic changes in mother.

Massive PPH is defined as loss of >1000 or 1500ml of blood.

ACOG (American College of Obstetrics & Gynecology) defines PPH as blood loss which decreases the hematocit by 10% or needs a transfusion.

More than half of maternal deaths occurring within 24hrs of delivery are mostly due to PPH.

Causes of PPH:

1. Uterine atony
2. Genital tract trauma
3. Coagulopathy
4. Retained placenta
5. Uterine inversion.

Normally the control of hemorrhage following delivery is by contraction & retraction of myometrial fibres. This causes kinking of blood vessels & so cuts off

the blood flow to placental site. Failure of this mechanism resulting from disordered myometrial function is called uterine atony & is the most common cause of PPH.

Predisposing factors include,

- High parity
- Uterine over distention secondary to
    1. Multiple pregnancy
    2. Hydramnios
    3. Fetal macrosomia
- Prolonged labor
- Precipitate labor
- Anemia
- Chorioamnionitis
- Uterine abnormalities or fibroids
- Previous H/O PPH
- Uterine inversion
- Retained placenta
- Manual removal of placenta

Myometrial relaxants - $MgSO_4$, beta agonists, diazoxide, halothane, calcium channel blockers.

Mismanagement of third stage of labor

Operative vaginal delivery

Prophylactic management of PPH:

The aim in the management of PPH should be prediction & prevention.

1. Women at risk of PPH should be identified.
2. AMTSL is recommended.
3. Early sucking.

Therapeutic management of PPH:

It requires multidisciplinary team for optimum management. It involves simultaneous resuscitation of patient & identification of cause & instituting definitive treatment.

Resuscitation:

Quick assessment of

General condition

Blood loss

Call for assistance

To identify the cause:

1. Check the contractility of uterus.
2. Rule out lower genital tract lacerations.
3. Make sure the entirety of placenta & membranes.

DEFINITIVE TREATMENT FOR THE MANAGEMENT OF PPH

MEDICAL METHODS:

1. Intravenous infusion of 20-40 units of oxytocin in 500ml of normal saline.
2. Intramuscular PG F2alpha-250 microgm

Supplementary procedures

1. Catheterise the bladder.

2. Uterine massage, either manually (hand on the fundus) or bimanually (vaginal hand in the anterior fornix; abdominal hand on the posterior aspect of the fundus) is a simple and very effective first line measure and reduces bleeding even if the uterus

remains atonic, allowing resuscitation to take effect with a reduced blood loss. If uterine atony continues after oxytocics are given, bimanual compression is undertaken.

3. Ensure appropriate oxygenation.

4. Give circulatory support as necessary with colloids or blood products.

5. Maintain communication between anaesthetist and rest of team.

SURGICAL MANAGEMENT

1. The tamponade test with Senkstaken-Blackmore tube or Rusch balloon catheter.

2. Laparotomy

a) If bimanual compression of uterus reduces the bleeding, brace sutures can be applied.

B-lynch sutures

Multiple square sutures

b) If PPH follows placenta previa, apply

Isthumus - cervical apposition sutures

Undersuturing of placental bed

c) If bimanual compression fails to control bleeding, following procedures to be undertaken.

Stepwise ligation of blood vessels including

Uterine artery

Ovarian artery

Descending cervical artery

Internal iliac artery ligation

Unilaterally followed by the opposite side

d) Uterine artery embolization

e) Hysterectomy-which is the last resort.

THIRD STAGE OF LABOR

THIRD STAGE OF LABOR

The third stage of labor is the time interval between delivery of baby and expulsion of placenta. During this stage the muscles of uterus contract downward, & the placenta begins to separate from the uterine wall. The amount of blood lost depends on how quickly this occurs. If the uterus does not contract normally (uterine atony), the blood vessels at the placental site remain open, & severe bleeding results.

PHYSIOLOGY:

Normal volume of blood flow through the placenta at term is 700ml/minute. This has to be arrested within seconds following placental separation, otherwise serious hemorrhage will occur. The three interrelated physiological mechanism responsible for arrest of hemorrhage are,

1. Retraction of oblique muscle fibres in upper segment which acts as a ligature to the torn vessels that intervene through the muscle.

2. Following separation, the strong uterine contraction brings the uterine walls into apposition so that further pressure is exerted on the placental site.

3. There is transitory increase in activation of coagulation & fibrinolytic system around the placental site. So clot formation in the torn vessels is intensified. Placental site is covered by fibrin mesh utilizing 5-10% of circulating fibrinogen.

Any impairment in these mechanisms predisposes to severe PPH.

MECHANISM OF PLACENTAL SEPARATION:

Schultz mechanism:

During the process of separation, there is formation of retroplacental hematoma. First the central portion, later the rest of placenta is delivered inversely. So the fetal surface appears first with the membranes covering the maternal surface.

Duncan mechanism:

Edge of placenta separates first & the maternal surface appears at the vaginal outlet.

ACTIVE MANAGEMENT OF THIRD STAGE OF LABOR (AMTSL)

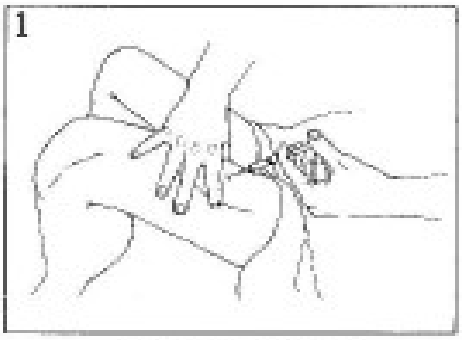
AMTSL is an effective measure of preventing PPH. AMTSL can be practiced wherever women give birth, including at home, by trained health care providers linked to essential supplies. AMTSL speeds delivery of the placenta by increasing uterine contractions and prevents PPH by averting uterine atony.

The components of AMTSL are:

1. Administration of an uterotonic agent within one minute after the baby is born.
2. After the cord is clamped, delivery of placenta by controlled cord traction (gently pulling on the umbilical cord) with counter traction on the fundus.
3. Fundal massage after delivery of placenta.

Uterotonic drugs:

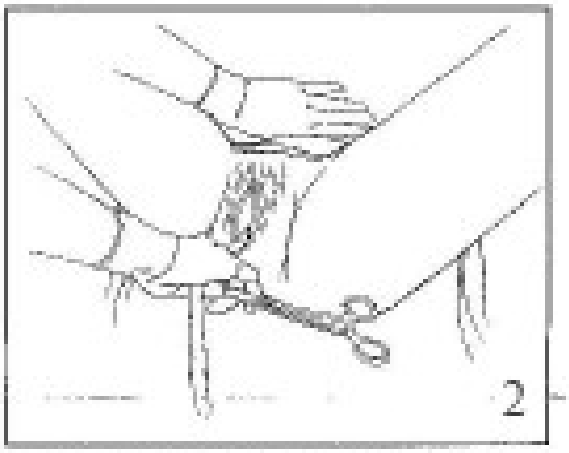
An uterotonic drug stimulates uterine contractions. Routine administration of a uterotonic drug is an integral part of AMTSL & is thought to play the largest role in preventing PPH. Injectable oxytocin is preferred over other uterotonic drugs because it is effective quickly-2 to 3 minutes after injection; it has minimal side effects, & all women can use it. If oxytocin is not available, other uterotonics may be used,such as injectable ergometrine, injectable syntometrine, or oral misoprostol. Injectable uterotonic drugs require proper storage to retain potency & prolong shelf life.



Give oxytocin within
1 minute of delivery of baby

Controlled Cord Traction:

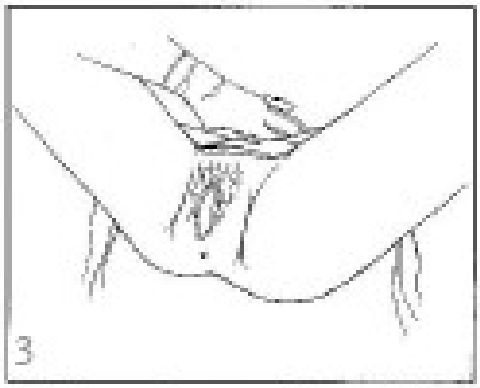
The border of one hand is placed on the mother's abdomen below the level of uterine fundus suprapubically & the other hand grasps the umbilical cord & applies steady traction posteriorly & downwards while the uterus is being held upward to prevent uterine inversion



Deliver the placenta by controlled traction on the umbilical cord and counter-pressure to the uterus

Fundal Massage:

The fundus of the uterus can be felt through the wall of the abdomen.



Massage the uterus through the abdomen after delivery of the placenta

PHARMACOLOGY OF UTEROTONICS:

The primary mechanism by which hemostasis is achieved at the site of placental separation during 3rd stage of labor is compression of blood vessels by well contracted myometrium. The following drugs are used in various ways to promote myometrial contractions. They are given alone or in combination.

1. Oxytocin
2. Methylergometrine
3. Syntometrine

OXYTOCIN:

The synthetic form of the octapeptide of oxytocin is commercially available as syntocinon or pitocinon. The half life of i.v oxytocin is 3-5mts.

Onset of action:

Intravenous - within 30-40 seconds

Intramuscular - after 3 minutes

Mechanism of action:

It increases the frequency & strength of uterine contraction & augments retraction of uterus.

No absolute contraindications for its use.

Deleterious effects can occur with inadvertent use of i.v oxytocics.

1. In utero death of fetus
2. Rupture uterus

Side effects:

1. Maternal hypotension
2. Cardiac arrhythmias
3. Water intoxication

Water intoxication occurs when the rate of infusion is more than 40mU/mt & oxytocin is administered in large volumes of electrolyte free solution (Whalley & Pritchard 1963)

It should not be given i.v as a large bolus but rather as a much more dilute solution by continuous i.v infusion.

When oxytocin is to be administered in high doses for a considerable period of time, it should be used either in normal saline or ringer lactate solution.

SYNTOMETRINE:

Each 1 ml ampoule of injectable solution contains 5 IU synthetic oxytocin & 0.5 mg ergometrine maleate. Syntometrine injection is a clear, colorless solution, & contains maleic acid as a buffer, pH 3.2. The ampoules have two green identification rings.

Pharmacology:

Syntometrine combines the rapid uterine action of oxytocin, a nonapeptide hormone released by the posterior lobe of pituitary, with the sustained uterotonic effect of ergometrine.

Following intramuscular administration, the latent period for the occurrence of the uterine response is considerably shorter with syntometrine (about 2 ½ minutes) than with ergometrine given alone (about 7 minutes), whereas the uterotonic effect of syntometrine lasts for several hours compared with only ½ to 1 hour when oxytocin is given alone.

These properties make syntometrine i.m suitable for the active management of third stage of labor and for the prevention or treatment of postpartum hemorrhage, particularly in situations where for any reason the intravenous administration of an uterotonic agent is impracticable.

Indications:

1. Active management of third stage of labor (as a means to promote separation of placenta and to reduce blood loss)
2. Prevention and treatment of postpartum hemorrhage associated with uterine atony.

Contraindications:

Hypersensitivity to any one of the components

First stage of labor

Second stage of labor before crowing of baby's head

Failure of the uterus to contract normally during labor

Severe kidney disorders

Severe liver disorders

Severe heart disorders

Vascular disease

Very high blood pressure

Pre-eclampsia or eclampsia

Infection of blood (septicaemia or blood poisoning)

Caution is required in patients with respiratory disease and chronic anaemia.

Interactions:

Syntometrine may enhance the pressor effect of vasoconstrictor drugs (e.g. of sympathomimetic agents contained in local anaesthetics) and potentiate the uterine action of prostaglandins.

Halothane anaesthesia may diminish the uterotonic effect of syntometrine.

Adverse effects:

Syntometrine may cause nausea, vomiting, uterine hypertonicity associated with abdominal pain, headache, dizziness and skin rashes. On rare occasions, it may give rise to hypertension, bradycardia, cardiac arrhythmias, chest pain or to anaphylactoid reactions associated with dyspnoea, hypotension, collapse or shock.

DOSAGE:

1ml intramuscularly following delivery of anterior shoulder, or immediately after delivery of child. Expulsion of placenta, which is normally separated by first strong uterine contraction following the injection of syntometrine should be manually assisted by applying gentle fundal pressure.

Drug	Transport	Storage
Oxytocin	Unrefrigerated transport is possible if no more than one month at 30°C.	▪ Check manufacturer's recommendations – some manufacturers are producing oxytocin that is more heat stable than previously available ▪ Temporary storage outside the refrigerator at a maximum of 30°C is acceptable for no more than three months. ▪ If possible, keep refrigerated at 2–8°C.

Syntometrine	Unrefrigerated transport in the dark is possible if no more than one month at 30°C. Protect from freezing.	▪ Store in the dark. ▪ Keep refrigerated at 2–8°C. ▪ Store in closed container. ▪ Protect from freezing.

PREVENTION AND TREATMENT OF PPH:

1 ml of oxytocin i.m should be given following expulsion of placenta, or when bleeding occurs.

If necessary, the injection may be repeated after an interval of not less than 2 hrs. The total dose given within 24 hrs should not exceed 3ml.

Intravenous administration of syntometrine (0.5 to 1ml by slow injection) is possible, but not generally recommended. It is advisable to monitor blood pressure during intravenous administration.

AIM OF THE STUDY

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This study compares the efficacy of Syntometrine versus Oxytocin in the active management of third stage of labor in reducing the risk of PPH and other adverse third stage outcomes.

MATERIALS AND METHODS

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STUDY DESIGN:

Prospective case control study.

SETTINGS:

This randomized prospective comparative study was conducted at Institute of Social Obstetrics and Govt. Kasturba Gandhi Hospital for Women and Children, Triplicane, Chennai, on three hundred patients, who were admitted in labor ward with no known risk factors for PPH.

DURATION OF STUDY:

From September 2008 to August 2009

METHODOLOGY:

All patients included in the study delivered vaginally .The patients were assigned to 2 groups at random of 150 patients in each group.

GROUP 1:

Syntometrine 1 ampoule is administered within one minute after delivery of the baby.

GROUP 2:

Oxytocin 10 units is administered within one minute of delivery of the baby.

INCLUSION CRITERIA:

1. Singleton pregnancy
2. No contraindication for oxytocin/syntometrine
3. No obstetric or other indication that could warrant abdominal delivery
4. No known risk factor for PPH

EXCLUSION CRITERIA:

1. Previous Caesarean section
2. Previous scarred uterus
3. Multiple pregnancy
4. Cardiac patient
5. Hepatic disorders
6. Disorders of blood coagulation
7. Past H/o third stage complications
8. Known risk factors for PPH
9. Instrumental vaginal delivery

10. Absolute or relative risk factors for spontaneous vaginal delivery and hence posted for elective CS.

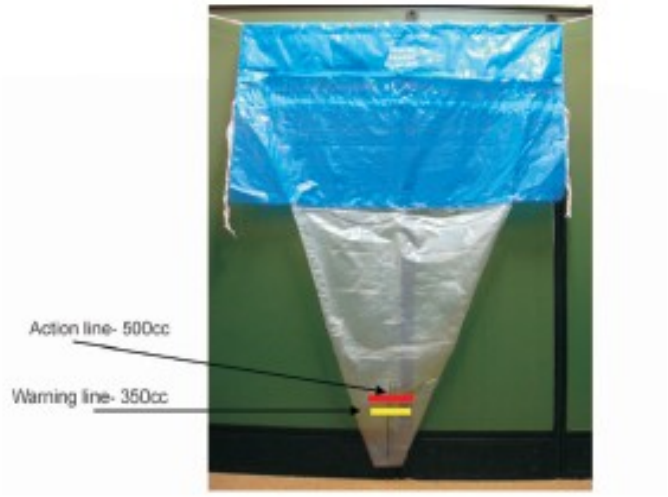
TOTAL NUMBER OF CASES:

Three hundred patients

PROCEDURE:

The delivery was effected with the patient at the edge of the table within 1 minute of delivery of the baby, either 10 units of injection oxytocin or 1 ampoule of syntometrine were given in a randomized order. The user will be unaware of the drug being given since all these drugs will be of the same color and the ampoules will only be marked with appropriate numbers and no names will be mentioned. Once the placenta is removed, she was placed over a blood drape, which is a disposable, conical, graduated plastic collection bag.

The amount of blood collected in the blood drape is measured. The average immeasurable blood loss due to episiotomy was taken as 50ml and the same is not included in the blood loss. Similarly when there was profuse bleeding following episiotomy, such patients were excluded from the study.


Action line- 500cc
Warning line- 350cc


6
Look at amount of blood
in funnel

RESULTS AND ANALYSIS

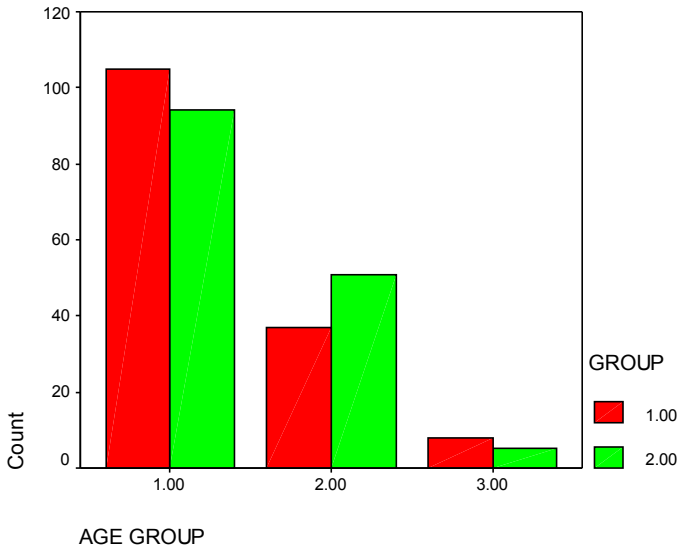
RESULTS AND ANALYSIS

This study was commenced with 300 women and the outcome was analyzed using various parameters. The results were subjected to statistical analysis using the t test and chi square test.

AGE GROUP:

TABLE 1:

Age group	Legend	Syntometrine group (group 1)		Oxytocin group(group2)		Total
		Frequency	Percentage	Frequency	Percentage	
<25yrs	1	105	70%	94	62.7%	199(66.3%)
26-30yrs	2	37	24.7%	51	34%	88(29.3%)
>30yrs	3	8	5.3%	5	3.3%	13(4.3%)
TOTAL		150	100%	150	100%	300(100%)



Most of patients in both groups were in age group of <25yrs. 70% of cases in Group 1 & 62.7% of cases in Group 2 were in age group <25yrs. Only 5.3% of cases in Group 1 & 3.3% of cases in Group 2 were in age group >30yrs.

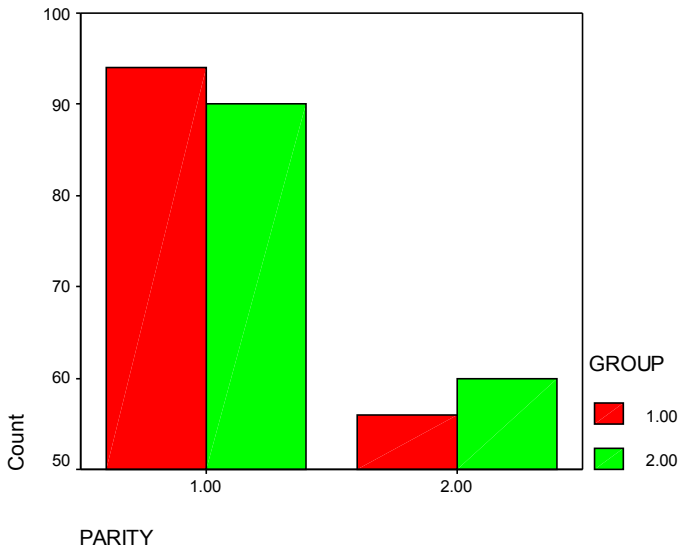
PARITY:

62.7% of women in Group 1 & 60% of cases in Group 2 were primigravida. 37.3% of cases in Group 1 & 40% of cases in Group 2 belonged to multigravida.

TABLE 2:

Parity	Legend	Syntometrine group		Oxytocin group		Total (%)
		Frequency	%	Frequency	%	
Primigravi	1	94	62.7%	90	60	184

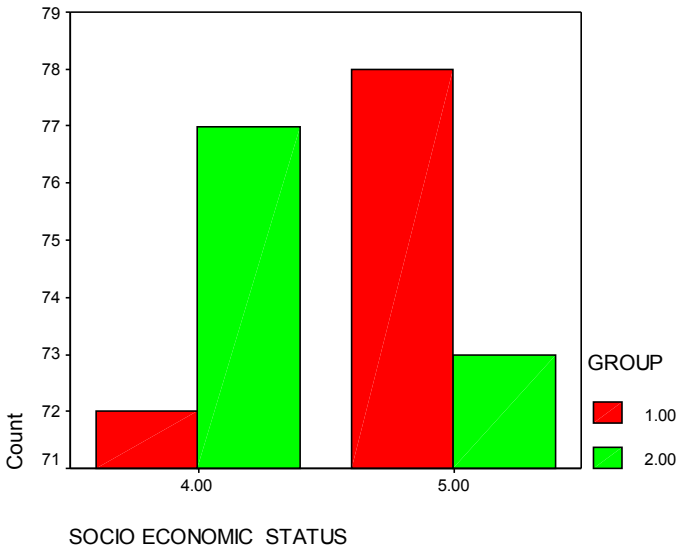
da						(61.3 %)
Multigravida	2	56	37.3%	60	40	116 (38.7 %)
Total		150	100%	150	100%	300 100%



SOCIOECONOMIC STATUS:

TABLE 3:

Socioeconomic Status	Legend	Syntometrine Group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Class 4	4	72	48%	77	51.3%	149 49.7%
Class 5	5	78	52%	73	48.7%	151 50.3%
Total		150	100%	150	100%	300 100%



48% of cases in group 1 & 51.3% of cases in group 2 belonged to class 4 socioeconomic status. 52% of cases in group 1 & 48.7% of cases in group 2 belonged to class 5 socioeconomic status.

BOOKING:

All patients in our study group were booked cases, though they were selected at random basis.

TABLE 4:

Booking	Legend	Syntometrine group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Booked	1	150	100%	150	100%	300 100%
Unbooked	2	0	-	0	-	
Total		150	100%	150	100%	300 100%

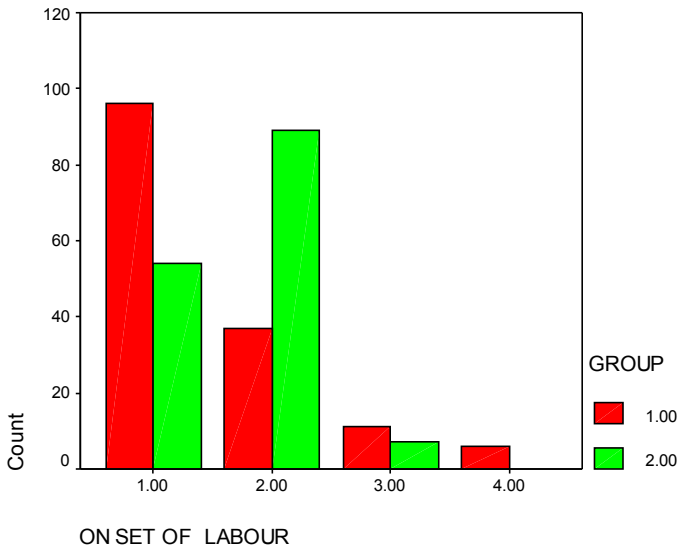
ONSET OF LABOR:

TABLE 5:

Onset of labor	Legend	Syntometrine group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Spontan Eous	1	96	64%	54	36%	150 (50%)
Oxytocin Induction	2	37	24.7%	89	59.3%	126 (42%)
PGE2 gel Induction	3	11	7.3%	7	4.7%	18(6%)
PGE2 gel Followed	4	6	4%	0	0%	6(2%)

by oxytocin						
Total		150	100%	150	100%	300(100%)

The % is calculated for the individual number of cases in the respective groups (150 in each group) and for 300 cases in the grand total.



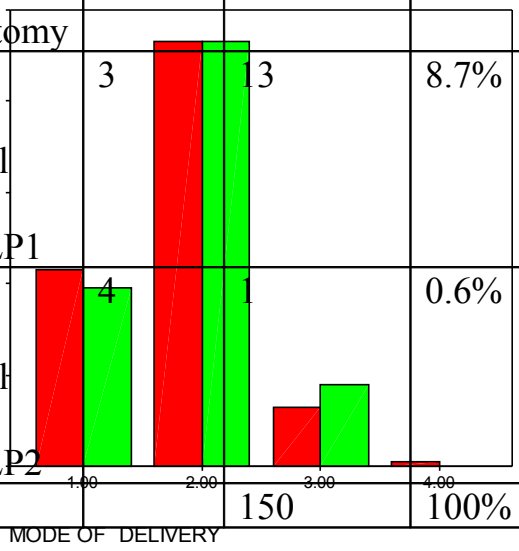
64% of cases in group 1 & 36% of cases in group 2 had spontaneous onset of labor. 24.7% of cases in group 1 & 59.3% of cases in group 2 were induced with oxytocin. 7.3% 0f cases in group 1 & 4.7% of cases in group 2 were induced with PGE2 gel. 4% of cases in group 1 & none of the case in group 2 were induced with PGE2 gel followed by oxytocin.

MODE OF DELIVERY:

Most of the cases in group 1 (62%) & group 2 (62%) were delivered by Labor natural with episiotomy.

TABLE 6:

Mode of Delivery	Legend	Syntometrine Group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Labor Natural	1	43	28.7%	39	26%	82(27.3%)
Labor Natural With Episiotomy	2	93	62%	93	62%	186(62%)
Labor Natural With LP1	3	13	8.7%	18	12%	31(10.3%)
Labor Natural With LP2	4	1	0.6%	0	0%	1(0.3%)
Total		150	100%	150	100%	300(100%)



DURATION OF THIRD STAGE OF LABOR:

TABLE 7:

	Frequenc	Mean duration of third

	y	Stage in minutes
Syntometrin e Group	150	11.86
Oxytocin group	150	11.74

The difference between mean duration of 3rd stage between two groups was 0.12 minutes, which is not statistically significant (p=0.816).

MEAN BLOOD LOSS:

TABLE 8:

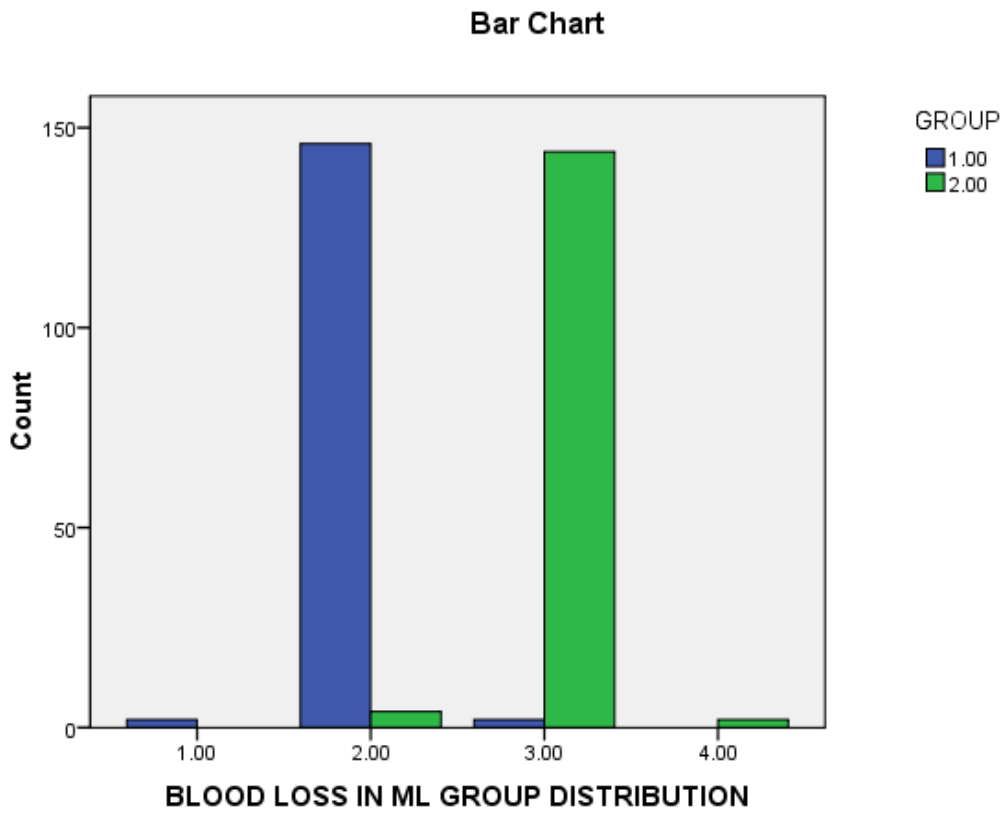
	Frequenc y	Mean blood loss in ml
Syntometrin e Group	150	120ml
Oxytocin group	150	171ml

The difference between mean blood loss between two groups was 51ml, which is statistically significant (p=0.000).

AMOUNT OF BLOOD LOSS IN GROUPS:

TABLE 9:

Blood loss In groups	Syntometrine group		Oxytocin group		Total
	Frequency	Percentage	Frequency	Percentage	
<100ml	2	1.3%	0	.0%	2 (0.7%)
100-150ml	146	97.3%	4	2.7%	150 (50%)
150-200ml	2	1.3%	144	96%	146 (48.7%)
>200ml	0	.0%	2	1.3%	2 (0.7%)
Total	150	100%	150	100%	300 (100%)

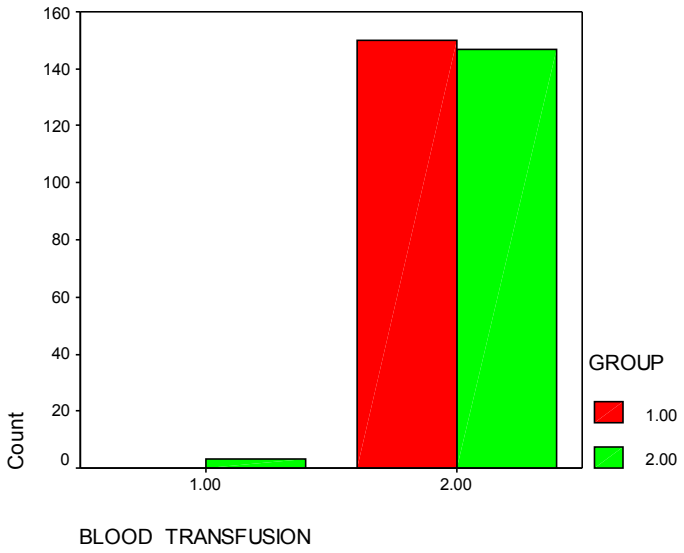


97.3% of cases in syntometrine group had blood loss between 100-150ml & 96% of cases in oxytocin group had blood loss between 150-200ml.

BLOOD TRANSFUSION:

TABLE 10:

Blood Transfusion	Legend	Syntometrine Group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Yes	1	0	0%	3	2%	3(1%)
No	2	150	100%	147	98%	297(99%)
Total		150	100%	150	100%	300(100)%)



2% of cases in group 2 & none of the case in group 1 had blood transfusion, which is not statistically significant (0.082).

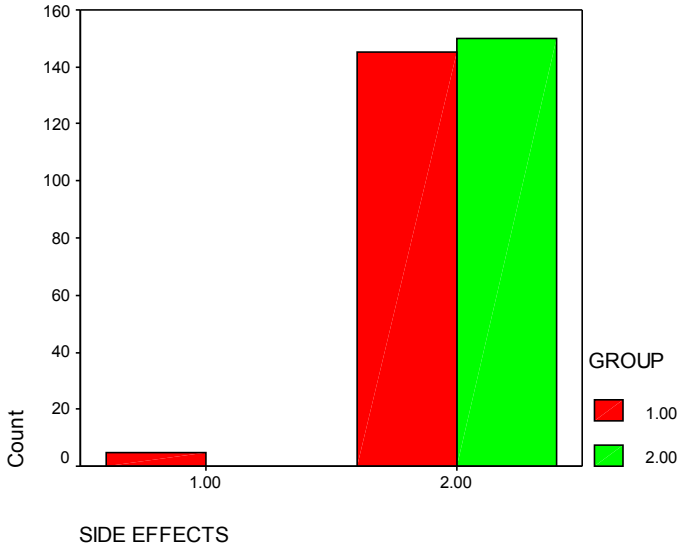
SIDE EFFECTS:

None of the case in group 2 had side effects, whereas in group 1, 3.3% of cases developed adverse effects like nausea & vomiting.

TABLE 11:

Side effects	Legend	Syntometrine		Oxytoin Group		Total

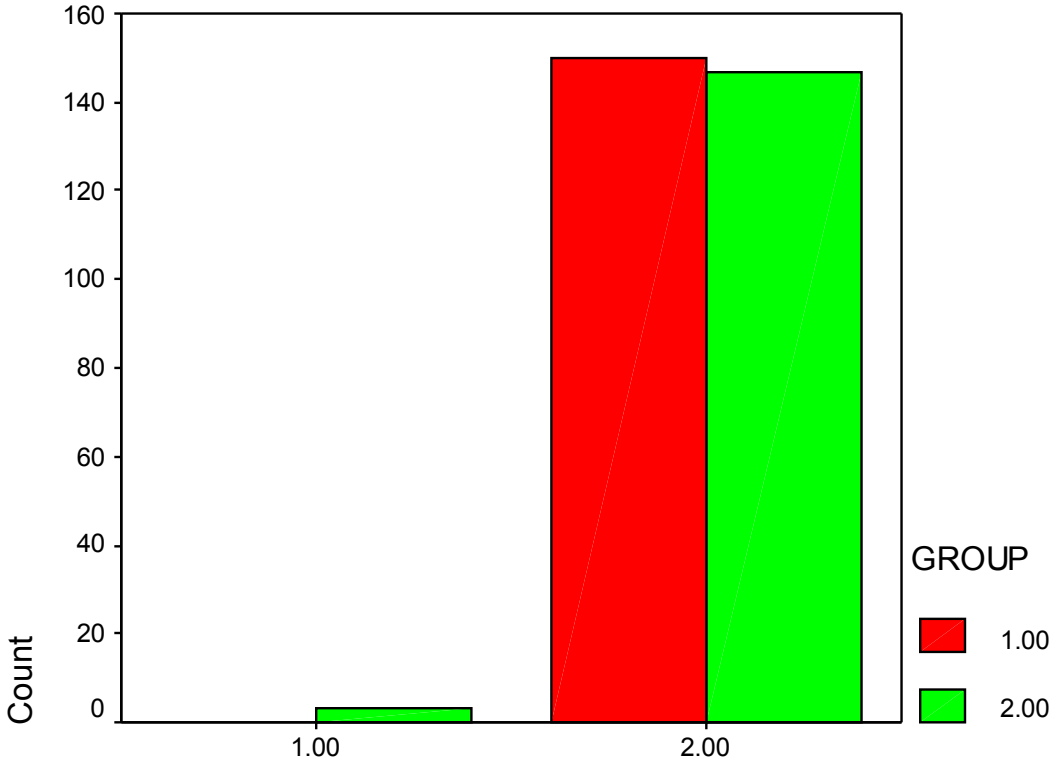
		Group				
		Frequency	Percentage	Frequenc y	Percentage	
Yes	1	5	3.3%	0	0%	5 1.7%)
No	2	145	96.7%	150	100%	295 98.3%
Total		150	100%	150	100%	300 100%



DROP IN HEMOGLOBIN OF 0.7 TO 1 GRAM PERCENT:

TABLE 12:

↓Hemoglobin in Grams percent	Legend	Syntometrine Group		Oxytocin Group		Total
		Frequency	Percentage	Frequency	Percentage	
Yes	1	0	0%	3	2%	3 1%
No	2	150	100%	147	98%	297 99%
Total		150	100%	150	100%	300 100%



DROP IN HEMOGLOBIN TO 0.7 TO 1 GRAM PERCENT

Only 2% of cases in group 2 had drop in hemoglobin level of 0.7 to 1grams percent after delivery, which is not statistically significant (p=0.082).

BIRTH WEIGHT OF THE BABY:

The mean birthweight of the baby in both groups was 3.1kg.

TABLE 13:

	Frequenc y	Mean weight In kg
Syntometrin e Group	150	3.1
Oxytocin group	150	3.1

DISCUSSION

DISCUSSION

This randomized prospective study compares the efficacy of syntometrine versus oxytocin in active management of third stage of labor.

Postpartum hemorrhage is an important cause of maternal morbidity and mortality, especially in developing countries where up to 28% of maternal death are attributed to this cause (Walder, 1997). The prophylactic use of oxytocics in the third stage of labor has been found to decrease the rate of postpartum bleeding by 38%. However, there is no agreement regarding the type and route of administration of oxytocic drugs which offers the best efficacy and safety profile.

Several controlled trials examining the alternative oxytocic preparations used routinely in the management of third stage of labor suggested that a mixture of oxytocin and ergometrine (Syntometrine) might be the drug of choice. However, the administration and storage of syntometrine may not always be possible in some hospitals or rural communities due to discontinuous supply of disposables or refrigeration equipment.

A case control study[28] was carried out at Jinnah Postgraduate Medical in Department of Gynecology and Obstetrics, Karachi from January 2002 to December 2002. Three hundred patients were selected by non-probability convenience sampling. The patients were grouped in three categories. Group 1 comprised of 150 patients who received syntocinon & group 2 comprised of 150 patients who received syntometrine i.m after placental expulsion. The average age in group 1 was observed 27.49±6.58 (ranging from 17 to 43) years while in group 2, it was 27.17±6.27 (ranging from 16 to 47) years.

The number of women who were primigravida in group 1 were 44/150 (29.3%) and 47/150 (31.1%) in group 2. Overall incidence of gravidity in this study was 91/300 (30.3%) primigravida & 209/300 (69.7%) multigravida.

Blood loss was read in 3 ratings 300ml,500ml and >750ml. More than 500ml blood loss was observed 4.3%, with 4.7% in Group I and 4% in group 2. Thus a non significant difference was observed in both groups regarding the amount of blood loss>500ml ($p<0.05$). The rate of blood loss of 300 ml was noted in 48.7% of women in group 1 and 59.3% of women in group 2 which was statistically significant ($p<0.05$).

In our study, there was no statistically significant difference between the two groups with regard to maternal age and parity. 70% of cases in syntometrine group

and 62.7% of cases in oxytocin group were in age group of <25years. Parity status in our study observed that 184/300 (61.3%) was primigravidas and 116/300 (38.7%) was multigravida. The number of primigravida in group 1 was 94/150 (62.7%) and in group 2 was 90/150 (60%). Use of syntometrine as part of AMTSL was associated with statistically significant reduction in mean blood loss when compared with oxytocin (120 & 171ml respectively, p<0.000).

In a study[29] carried out at Queen Alia Military Hospital (QAMH) in Amman between 1st February to 30th April 1997, 583 women with a singleton pregnancy and normal vaginal delivery were randomly allocated to receive syntometrine (n=293) or oxytocin (n=290). Oxytocin augmentation was used in 200 (68%) and 198 (68%) in syntometrine and oxytocin groups respectively. Episiotomy was performed in 250 (85%) cases in syntometrine group and 260 (90%) cases in oxytocin group. The mean birth weight of the baby in both groups was 3.2kg.

In our study, 37 (24.7%) cases in Syntometrine group and 89 (59.3%) cases in oxytocin group were induced with oxytocin. 6 (4%) cases in syntometrine group and none of the patient in oxytocin group were induced with PGE2 gel followed by

oxytocin. Episiotomy was performed in 62% 0f cases in both groups. The mean weight of the baby in both groups was 3.1kg.

In a prospective randomized study (2002) carried out in a university teaching hospital in Hongkong, prolonged third stage>30minutes was reported in 2.8% of syntometrine group & 1.8% in oxytocin group.

In our study, the mean duration of third stage of labor was 11.86 minutes in syntometrine group and 11.74 minutes in oxytocin group.

Yuen et al (2002) reported a higher incidence of retained placenta associated with the use of syntometrine compared with oxytocin, but similar finding was not observed in the current study. This might be related to the different way of delivering the placenta. In that trial, the placenta was left to deliver on its own, a 'hands –off approach' whereas in our study the same was delivered by controlled cord traction. Such interventions allow the placenta to be delivered before the occurrence of uterine spasm, thereby reducing the incidence of retained placenta.

McDonald et al (1993) [30]conducted double blind randomized controlled trial to compare oxytocin alone & syntometrine for their effect in AMTSL. Incidence of

PPH was similar in both groups. But the use of syntometrine was associated with nausea, vomiting & increased B.P.

In our study only 5 cases (3.3%) in syntometrine group developed side effects like nausea, vomiting.

In a prospective randomized study[31] conducted in a university teaching hospital, Hong Kong a total of 991 women having a singleton pregnancy and vaginal delivery were randomized by a computer generated number to receive either 1ml syntometrine i.m or 10 units of syntocinon after delivery of the shoulder of fetus. Seven patients in syntometrine group & four patients in syntocinon group failed to have a paired hemoglobin test to measure the change in hemoglobin 24 hours after delivery. There is no difference in the change in hemoglobin levels between 2 groups. The mean level of fall in hemoglobin was 0.8grams% in syntometrine group and 1grams% in oxytocin group.

In our study, none of the case in syntometrine group had a fall in hemoglobin delivery. 2% of cases in oxytocin group had a fall in hemoglobin level of 0.7 to 1grams% after delivery. Measurement of the change of hemoglobin concentration before and after delivery is a more objective method in assessing the amount of blood loss. It is also clinically more important and relevant as it aids the decision for further effective management.

SUMMARY

SUMMARY

This is a comparative study regarding the efficacy of syntometrine versus oxytocin in AMTSL in reducing the mean blood loss and other adverse 3rd stage outcomes, carried out in ISO/KGH by blood drape which is a disposable, conical, graduated plastic collection bag.

In the study group of 300 patients, mean age in syntometrine group is 24.3yrs. The mean age in oxytocin group is 24.6yrs. In syntometrine group, 62.7% were primigravida & 37.3% were multigravida. In oxytocin group, 60% were primigravida & 40% were multigravida.

In present study, 48% of cases in syntometrine group & 51.3% of cases in oxytocin group were belonged to class 4 socioeconomic status. 52% of cases in syntometrine group & 48.7% of cases in oxytocin group were belonged to class 5 socioeconomic status. All 300 patients in our study were booked.

In the present study, 64% of cases in syntometrine group & 36% of cases in oxytocin group had spontaneous onset of labor. Most of the patients were delivered

by Labor natural with episiotomy (62%). The mean duration of 3rd stage of labor was 11.86minutes in syntometrine group & 11.74minutes in oxytocin group.

The mean blood loss in syntometrine group was 120ml & oxytocin was 171ml. 97.3% of cases in syntometrine group had blood loss between 100-150ml & 96% of cases in oxytocin group had blood loss between 150-200ml. The mean birth weight of the baby was 3.1kg in both groups.

In the present study,none of the case in oxytocin group & 3.3% of cases in syntometrine group developed side effects like nausea & vomiting. None of the case in syntometrine group & 2% of cases in oxytocin group were given blood transfusion. 2% of cases in oxytocin group & none of the case in syntometrine group had a drop in hemoglobin level.

CONCLUSION

CONCLUSION

Postpartum hemorrhage is a common and serious complication of third stage of labor resulting in anemia and inceased morbidity in puerperium.

Routine active management is superior to expectant management in terms of blood loss, postpartum hemorrhage and other serious complications of third stage of labor.

Active management should be the routine management of choice for women expecting to deliver a baby by vaginal route in a health care facility.

The components of active management of 3rd stage includes giving oxytocics within 1 minute of birth of newborn, clamping and cutting of umbilical cord soon after birth, placental delivery by controlled cord traction with simultaneous counter traction to the uterine fundus.

The choice of drug depends on cost, facilities for storage and refrigeration, availability of trained personnel and assessment of trade-off between benefits and side effects.

Ergometrine and oxytocin have been used for a long time in markedly different doses and routes of administration with varying success.

The use of syntometrine as part of routine AMTSL appears to be associated with a statistically significant reduction in mean blood loss when compared to oxytocin.

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ANNEXURE

ANNEXURE

COMPARATIVE EFFICACY OF SYNTOMETRINE VERSUS OXYTOCIN IN ACTIVE MANAGEMENT OF THIRD STAGE OF LABOUR

Name of patient :

Age :

OP No. :

Socio Economic Status : I II III IV V

Education :

Address :

Obstetric Formula :

Booking : Booked/Unbooked

Onset of labor : 1. Spontaneous

2. Oxytocin induction

3. PG E2 gel induction

4. PG E2 gel induction followed by syntocinon

Mode of delivery : 1. Labor natural

2. Labor natural with episiotomy

3. Labor natural with LP 1STdegree

4. Labor natural with LP 2nd degree

Duration of 3rd stage in minutes:

Blood loss in ml :

Blood transfusion : Yes/No

Side effects : Yes/No

Drop in hemoglobin level : Yes/No

Baby weight :

MASTER CHART